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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,885	07/03/2003	Lennart Olsson	REC-105/US	6628

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EXAMINER

KOSAR, ANDREW D

ART UNIT PAPER NUMBER

1654

DATE MAILED: 03/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/612,885	Applicant(s) OLSSON ET AL.	
	Examiner Andrew D Kosar	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 16-26 is/are pending in the application.
- 4a) Of the above claim(s) 1-13 and 16-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim 15 has been cancelled by amendment, filed November 12, 2004, and a supplemental reply on January 5, 2005 is acknowledged.

Claims 1-14 and 16-26 are pending.

Election/Restrictions

Applicant's election with traverse of **Group II** (claim 14 and new claim 26) in the reply filed on November 12, 2004, and a supplemental reply on January 5, 2005 is acknowledged. The traversal is on the ground(s) that administration of PKC inhibitors is speculative, and without certainty, for modulation of EPOR. Applicant further asserts that the focus should be on small molecules that modulate by directly binding in to the EPOR. Applicant has not provided evidence to rebut the *prima facie* case. However, in response to Applicant's assertion that the focus should be on the small molecule interaction, one could administer PAMAM-HMB or any of compounds 1-5 to modulate EPOR (SA Qureshi, et al. PNAS (1999) 96, 12156-12161). In response to Applicant's assertion that the products are made *per se* by the methods, the methods are drawn to various effects elicited by the asserted product formation, and does not include a step of isolation of the product, and thus the methods do not explicitly form the products of Group I.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-13 and 16-25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed November 12, 2004, and a supplemental reply on January 5, 2005.

Claims 14 and 26 have been examined on the merits.

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Specification

The disclosure is objected to because of the following informality:

The specification recites "19xx" as the year of a Prior Art reference, e.g.- paragraphs [0006] and [0008], which should be a specific calendar year.

Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 14 and 26 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 33, and 35 of copending Application No. 10/613,754. Although the conflicting claims are not identical, they are not patentably distinct from each other because the combination of '754 is necessarily produced by the instantly claimed method, in that a 'combination' of the diazolohehexahydroquinoline and the modulating sequence of EPOR is required for the EPOR to be modulated. One could not practice the instantly claimed method without producing the product of '754.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Allowable Subject Matter

The prior art does not teach or suggest, alone or in combination, a method of the modulating EPOR with diazohexahydroquinoline compounds.

Boger and Goldberg (Bioorg. Med. Chem. (2001) 9, 557-562); DM Wojchowski, et al. (Exp. Cell Res. (1999) 253, 143-156); Qureshi, et al. (Proc. Natl. Acad. Sci USA (1999) 96, 12156-12161); and Tilbrook and Klinken (Intl. J. Biochem. Cell Biol. (1999) 31, 1001-1005) provide teachings on EPOR, EPO, and the state of the art with regards to EPO mimetic compounds and EPOR agonists/antagonists. They do not teach or suggest the instant method of modulating EPOR with diazohexahydroquinoline compounds.

US Patents 4,546,104 and 5,942,520 teach compounds related compounds, but do not teach or suggest, alone or in combination, the instantly claimed method with diazohexahydroquinoline compounds.

Proposed Claim Amendments

While it is clear that the method is for modulating the activity of EPOR by forming a complex of EPO-R and the compound, **Claim 14** is suggested to be amended in the following manner: “A method for modulating the activity of EPO-R, present as a cell membrane component comprising: forming [[a]] an EPO-R:diazohexahydroquinoline complex by [[bringing together]] contacting said EPO-R [[and]] with an effective amount of a diazohexahydroquinoline of the formula”. The proposed amendments find support in the specification, and more explicitly recite what is implicit in the claim.

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Conclusion

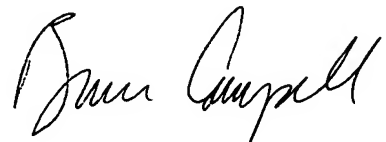
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew D Kosar whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 8am-430pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571)272-097474. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Andrew D. Kosar, Ph.D.
Patent Examiner
Art Unit 1654



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